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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT PAPER NUMBER

1647

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/028,072

Applicant(s)

BAKER ET AL.

Examiner

Jegatheesan Seharaseyon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/24/02: 10/15/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's preliminary amendment filed on 6 June 2002 is acknowledged and entered. Following the amendment, the original claims 1-71 are canceled, and the new claims 72-84 are added. Claims 72-84 are pending and under consideration. Currently, claims 72-84 are pending and under consideration. The claims are drawn to PRO3574 polypeptide SEQ ID NO: 4.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Information Disclosure Statement

3. The information disclosure statement, filed 7/24/2002 and 10/15/2002, have no blast searches. Thus, the Examiner cannot determine the merits of the blast search results.

Priority Determination

4. The claimed protein has no utility, see rejection below. Accordingly, priority is set at the instant filing date, 12/19/01.

Should the applicant disagree with the examiners factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to the date recited above which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of, and fully enabled for, prior to that date.

Claim Rejections - 35 USC § 112

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5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 72-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The protein identified as PRO3574 is not disclosed as being expressed on a cell surface. Accordingly, the limitation that the claimed protein comprises an "extracellular domain" (for example see claim 1 parts (c) and (d)) is indefinite, as the art does not recognize soluble proteins as having such domains. Further, if the protein had an extracellular domain, the recitation of "the extracellular domain"... "lacking its associated signal sequence" (claim 1, part (d), for example) is indefinite as a signal sequence is not generally considered to be part of an extracellular domain, as signal sequences are cleaved from said domains in the process of secretion from the cell.

Rejections under 35 U.S.C. §101 and §112:

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 72-84 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility.

The claims are directed to isolated polypeptides having at least 80% identity to SEQ ID NO: 4 with or without its signal peptide, or to the extracellular

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domain of SEQ ID NO: 4 with or without its signal peptide or the amino acid sequence of the polypeptide encoded by the full-length coding sequence of the cDNA deposited under ATCC Accession NO: 203654. Finally, claims are presented to chimeric proteins comprising the aforementioned polypeptides. The specification contains numerous asserted utilities for the claimed polypeptides, including use to identify molecules that bind to PRO3574 (including agonists and antagonists), used diagnostically or therapeutically, as molecular weight markers, binding agents, and for the production of antibodies. The utilities that pertain solely to polynucleotides (e.g. hybridization, chromosome and gene mapping, anti-sense) would not convey utility to the encoded protein. With respect to the remaining utilities, none of these asserted utilities is specific for the disclosed PRO3574 protein, as each of the aforementioned utilities could be asserted for any naturally occurring protein, and further, as none of the asserted utilities requires any feature or activity that is specific to the disclosed PRO3574.

The specification asserts that PRO3574 is an unspecified secreted transmembrane polypeptide. However, this family of proteins does not possess a common utility, but rather the proteins that can be broadly classified and have different activities, that confer different uses on them. Accordingly, the mere identification of a protein as belonging to a family, while indicative of evolutionary relatedness, is not indicative of function, nor by extension, of utility. The structure of the putative PRO3574 peptide is briefly discussed in Figure 4, as having putative transmembrane domains, corresponding to about amino acids 30-49, 81-100, 111-131 and 158-175. In addition, Applicants also describe potential N-

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glycosylation site around amino acids 9-13. Applicant has also described potential tyrosine kinase phosphorylation sites at amino acids 8-16 and 193-202. Further, potential N-myristoylation site around amino acids 68-74 has been described. However, there is no functional characteristic associated with these motifs, hence the mere observation that they exist is not probative of function or utility. Further, there is no disclosure that the protein is expected to be a secreted protein, nor of any extracellular domain. There is no biological activity, expression pattern, phenotype, disease or condition, ligand, binding partner, any other specific feature that is disclosed as being associated with PRO3574. Without any information as to the specific properties of PRO3574, the mere identification of such as having homology to a secreted transmembrane protein is not sufficient to impart any particular utility to the claimed polypeptides.

The polynucleotide (cDNA) encoding PRO3574 is disclosed to over express in breast tumor compared to the universal normal control based on the microarray analysis in Example 30 (see page 121, Table 8). Similarly, it is also disclosed that the polynucleotide is also over expressed in colon tumor compared to the matched normal colon (see page 121, Table 8). Table 8 also describes that many other proteins are over expressed in various tumors, based on which the specification made a general assertion that an over expressed protein in a diseased tissue is useful not only as a diagnosis marker for the presence of the disease condition, but also as a therapeutic target for treatment of the disease condition. The asserted utility in diagnosis and treatment is not substantial for the following reasons. The specification does not disclose the biological significance

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of this over expression, nor the correlation between the over expression of the PRO3574 and a predisposition to the onset of breast and colon tumors, i.e., whether it is the cause or the result of the tumors. Further, there is no supporting evidence to indicate that the polypeptide encoded by the polynucleotide of the instant invention is more highly expressed in tumor tissues compared to their normal tissue counterparts, and as such one of skilled in the art would conclude that it is not supported by a substantial asserted utility or a well-established utility.

Although, the specification claims that the polynucleotide is more highly expressed in the tumors of breast and colon, the specification does not teach what is the normal level of expression, does not indicate how high the expression level is compared to for example, normal breast tissue or colon; and does not provide a statistical correlation to the level of expression (for example, there is no indication of how many samples were compared to study the expression). Furthermore, even if the tumor is malignant, the specification fails to describe the type or kind of tumor present in breast and colon (for example, is it an adenocarcinoma or sarcoma etc.). Without knowing the identity of the tumors, one of skill in art cannot use the polynucleotides for diagnosis or therapeutic purposes as asserted. The specification does not disclose a correlation between any specific disorder and the altered level or form of the claimed polypeptides. In addition, the specification does not teach or describe the function of this yet to be identified polypeptide. With respect to the remaining utilities, none of these asserted utilities is specific for the disclosed PRO3574 encoding polypeptides, as each of the aforementioned utilities could be asserted for any naturally occurring

polypeptides, and further, as none of the asserted utilities requires any feature or activity that is specific to the disclosed PRO3574 polypeptides.

Cancerous tissue is known to be aneuploid, that is, having an abnormal number of chromosomes (see Sen, 2000, Curr. Opin. Oncol. 12: 82-88). The data presented in the instant specification are not corrected for aneuploidy. A higher amplification of a gene does not necessarily mean higher expression or lower expression in a tissue, but can merely be an indication that the cancer tissue is aneuploid. The preliminary data were not supported by further analysis of mRNA or protein expression, for example. Also, the literature reports that it does not necessarily follow that an increase in gene copy number results in increased gene expression and increased polypeptide expression, such that the claimed polypeptides would be useful for diagnosis of cancer or as a drug target. This fact is documented by Pennica et al. (1998, PNAS USA 95:14717-14722). In addition, they also observed that there was no correlation between WISP-2 mRNA expression and colon tumors. Furthermore they disclose that:

“An analysis of *WISP-1* gene amplification and expression in human colon tumors showed a correlation between DNA amplification and overexpression, whereas overexpression of *WISP-3* RNA was seen in the absence of DNA amplification. In contrast, *WISP-2* DNA was amplified in the colon tumors, but its mRNA expression was significantly reduced in the majority of tumors compared with the expression in normal colonic mucosa from the same patient.”

See p. 14722, second paragraph of left column; pp. 14720-14721, "Amplification and Aberrant Expression of *WISPs* in Human Colon Tumors." For example, *WISP-2* RNA expression was significantly lower in the tumor than the mucosa (see p. 14721). Therefore, data pertaining to PRO3574 polyucleotides do not necessarily indicate anything significant regarding the claimed PRO3574 polypeptides. Thus, the data does not support the implicit assertion that the nucleotide encoding PRO3574 can be used in cancer diagnosis or therapy. Significant further research would have been required of the skilled artisan to correlate the expression of PRO3574 in various disease and normal tissues to the extent that it could be used as a cancer diagnostic, and thus the implicitly asserted utility is not substantial.

The instant application has failed to provide guidance as to how one of skill in the art could use the claimed invention in a way that constitutes a substantial utility. The proposed uses of the claimed invention are simply starting points for further research and investigation into potential practical uses of the claimed the polypeptides. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner v. Manson*, 148 USPQ: at 696.

A substantial utility, by definition, is a utility the defines "real world" use, and a utility that requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use is not substantial utility. In the instant case, the over expression of the PRO3574 in breast and colon tumors (if

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significant), at the most, is an interesting invitation for further research, experimentation and confirmation as to whether the PRO3574 is useful as a diagnosis marker, or suitable as a therapeutic target for treatment of the tumors. These further research and experimentation, however, is part of the act of invention, and until it has been undertaken, the claimed invention is not considered substantial.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7a. Claims 72-84 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7b. Claims 72-77, 80, 81, 83 and 84 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure,

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physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

The claims are drawn to polynucleotides having at least 80%, 85%, 95% or 99% sequence identity with a particular disclosed sequence. The claims do not require that the claimed polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. The specification teaches that PRO3574 has (unspecified) homology to secreted and transmembrane polypeptides. The structure of the putative PRO3574 peptide is briefly discussed in Figure 4, as having putative transmembrane domains, corresponding to about amino acids 30-49, 81-100, 111-131 and 158-175. In addition, Applicants also describe potential N-glycosylation site around amino acids 9-13. Also, Applicant has described potential tyrosine kinase phosphorylation sites at amino acids 8-16 and 193-202. Further, potential N-myristoylation site around amino acids 68-74 has been described. However, there is no functional characteristic associated with these motifs, hence the mere observation that they exist is not probative of function or utility. Further, there is no disclosure that the protein is expected to be a transmembrane protein, nor of any extracellular domain.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of

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ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1616.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the human sequence.

In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Therefore, only isolated polypeptides comprising the amino acid sequence set forth in SEQ ID NO: 4, with or without the signal sequence, but not the full breadth of the claims meet the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written

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description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8a. Claims 72-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagase et al., Accession No: Q15012 or DNA Res. 2:37-43 (1995).

Nagase et al. describes cDNA sequences encoding amino acid sequence that has a 96% overall identity to SEQ ID NO: 4 (see Appendix A and B). Specifically, this protein has 100% sequence identity to the first 205 amino acids of the instant invention. Therefore, claims 72-75 are rejected as being anticipated by Nagase et al (1995).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions

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covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9a. Claims 79, 81, 83 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagase et al., Accession No: Q15012 or DNA Res. 2:37-43 (1995) in view of Jacobs et al. (U.S. Patent No: 5 965 397).

The teachings of Nagase et al. have been described above in paragraph 8a. However, Nagase et al does not teach the generation of a polypeptide lacking the signal sequence nor chimeric polypeptide with heterologous polypeptide containing an epitope tag or Fc region of an immunoglobulin. Jacobs et al. describe nucleotides that are capable of encoding secreted polypeptide. With respect to the limitation of "lacking its associated signal peptide" in claims 79 and 81, Jacobs et al. teaches recombinant expression of polypeptides, i.e., a vector comprising the cDNA, a host cell thereof and a method of making the polypeptide (claims 1-4 and columns 21, 24, lines: 31-53), the cDNA would produce the polypeptide of interest, but lacking its associated signal peptide when transfected into the host cell. It also describes fusion peptides containing Fc region thus meeting the limitations of claims 83 and 84 (column 21, lines 10-25). Therefore, it would have been *prima facie* obvious to

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the person of ordinary skill in the art at the time the invention was made to generate a polypeptide lacking its associated signal peptide as taught by Jacobs et al. by cloning the cDNA that generates a polypeptide, 96% identical to the instant invention (SEQ ID NO: 4) described by Nagase et al. into a vector, transfecting the vector containing the insert into host cells and making the polypeptide. Similarly, it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to generate chimeric polypeptide with heterologous polypeptide containing an epitope tag or Fc region of an immunoglobulin as taught by Jacobs et al. using the polypeptide described in Nagase et al. that is 96% identical to SEQ ID NO: 4 of the instant invention. The person of ordinary skill in the art would have been motivated to generate polypeptide lacking its associated signal peptide because it would improve the therapeutic value of the protein and will also help in the delivery to a specific target. The person of ordinary skill in the art would have also been motivated to generate heterologous polypeptides containing the polypeptide described by Nagase et al. because this will allow the one of skilled in the art to purify the expressed protein or to use in binding studies or diagnostic and therapeutic purposes. There is a reasonable expectation of success because generating polypeptide lacking its associated signal peptide and heterologous polypeptide is routine in the art for purification, expression studies and therapeutic purposes. Therefore, the claims 79, 81, 83 and 84 are rejected as obvious over Nagase et al., Accession No: Q15012 or DNA Res. 2:37-43 (1995) in view of Jacobs et al. (U.S. Patent No: 5 965 397).

Double Patenting

10. Claims 72-84 of this application conflict with claims 72-84 of Application No. 10/230,417. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 72-84 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 72-84 of copending Application No. 10/230, 417. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. In both instances the claims are directed to polypeptide of SEQ ID NO: 4 (PRO3574).

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Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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